

TO WHOM IT MAY CONCERN

UNDERSIGNED AUTHORITY, **SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA**
(SLOVAK CHAMBER OF COMMERCE AND INDUSTRY, SCCI),
a public legal institution from the Law No.9 / 1992 Coll. as amended and revised,
and on the basis of submitted documents

HEREBY CERTIFIES THAT:

- 1) A company **Chirana Progress, s.r.o.** (hereinafter referred as **MANUFACTURER**), headquartered in **Vrbovská cesta 17, PIEŠŤANY**, Postcode **921 01, Slovak Republic**, is the limited liability company established under the laws of the Slovak Republic on **January 20, 1998** and registered with the **District Court Trnava**, Section: Sro, Insert No. **10672/T**, with the subject matters: **manufacturing, repairing, distribution and sale of medical devices, instruments and medical supplies.**
- 2) **MANUFACTURER** has its Manufacturing plant in **Piešťany (SK)**.
- 3) Products made in the above Manufacturing plant, which are listed in the Annex of the **M&FSC**, comply with the requirements and standards for the safety of medical devices as required by applicable legislation of the Slovak Republic and the European Union, i.e.:
 - **Act no. 355/2007 Coll.** on Protection, Support and Development of Public Health and on Amendments and Supplements to Certain Acts, as amended
 - **Act no. 56/2018 Coll.** on product conformity assessment, making a determined product on the market and on the amendment of certain laws,
 - **Act no. 362/2011 Coll.** on medicines and medical devices and on amendments to certain laws, as amended;
 - **Gov. Regulation no. 582/2008 Coll.** as amended by **2015/2013 Coll.** laying down details on European technical requirements and conformity assessment procedures for medical devices (MDs) **Class II b** under **Annex II of the Medical Device Directive no. 93/42/EEC** and **Directive no. 2011/65/EU**;
4. The Manufacturing Plant is the holder of (i) the **Certificate No. Q-0161/18 of Quality Management System** according **ISO 9001:2015** (valid until March 26, 2021), (ii) **Certificate No. M-0102/18 of Medical Devices-Quality Management Systems** according **EN ISO 13485:2016** (valid until March 26, 2021) and (iii) **EC Certificate No. 2018-MDD/QS-007 of the Quality Assurance System** (valid until April 16, 2023), according Annex II, Section 3.3, and 5, of the Directive no. 93/42/EEC as amended by Directive 2007/47/EC, all issued by **3EC International a. s., Bratislava, Slovakia**, Notified Body No. 2265 (Reg. No. 305/Q-054 and Q-055, accredited by SNAS).
- 5) **MANUFACTURER** prepared technical documentation, prepared and issued **EC Declaration of Conformity** for the MDs and affixed with the **CE mark** under the **Medical Device Directive no. 93/42/EEC** and therefore the MDs maybe freely sold in all member states of the European Economic Area including the Slovak Republic.
- 6) This Free Sales Certificate for the MDs listed in the Annex is issued to the **MANUFACTURER** on its request. Export of the MDs outside EU is not prohibited.

Bratislava, 25 -03- 2019

(Place and date)



Juraj Knopp

(Name, signature of competent officer of SCCI)

Continue

Annex to Certificate of M&FS:

LIST OF MEDICAL DEVICES
of Chirana Progress, s.r.o., Piešťany, Slovakia
/MANUFACTURER/

Item:	List of medical devices (MDs) (product name and Model)	MD Reg. no./ SIDC	MD Class	EC DoC No./ issued:
1.0	<u>HYDROTHERAPY EQUIPMENT:</u>			
1.1.1	LAGUNA, LAGUNA PLUS, LAGUNA BUBBLE, LAGUNA PLUS BUBBLE	P 22650	II. a	EC Declaration of Conformity No. CE-VO-12 according Annex VII of the Directive 93/42 EEC as amended/ Issued by Chirana Progress, s.r.o. on 19.03.2019
1.1.2	LAGUNA TORNADO	P 22654		
1.2.1	OCEAN ECONOMY, OCEAN STANDARD, OCEAN FORTE	P 22654		
1.2.2	OCEAN DE LUXE,	P 22653		
1.3.1	CASCADE, CASCADE PLUS, CASCADE DE LUXE	P 22653		
1.3.2	CASCADE SENIOR	P 26217		
1.4.1	LASTURA	P 26218		
1.4.2	LASTURA PROFI	P 26217		
1.4.3	LASTURA HOBBY	P 22562		
1.5.1	CORAL, CORAL ECONOMY	P 22562		
1.5.2	CORAL LYMFO	P 26215		
1.6.1	HUBBARD BATH; HUBBARD BATH PLUS	P 26215		
1.7.1	VOD 56, VOD 56 HT	P 26216		
1.8.1	NIAGARA, NIAGARA PLUS	P 28886		
1.9.1	ELECTRA, ELECTRA CG	P 10403		
	XXXXXXXX			